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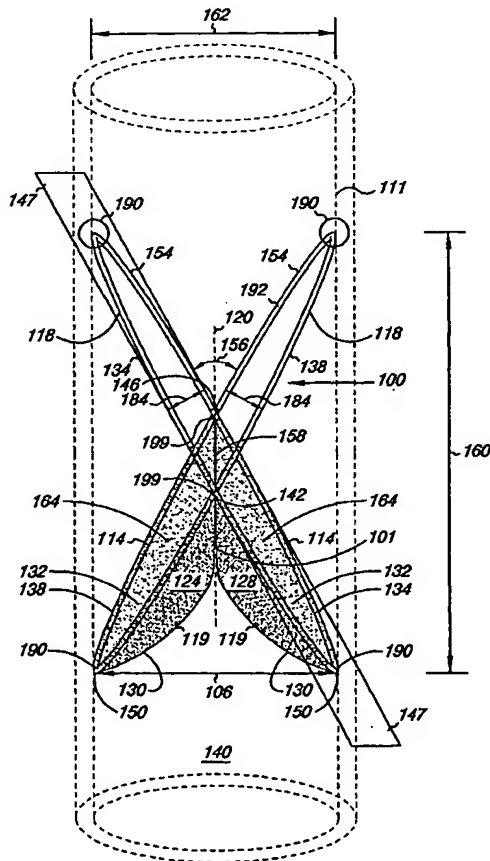
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(54) Title: **VENOUS VALVE APPARATUS, SYSTEM, AND METHOD**



(57) Abstract: A venous valve (100) apparatus, System and method for valve replacement. The valve includes a valve frame (114), a valve leaflet joined (119) to the valve frame, and a support frame (118). The valve leaflet includes surfaces defining a reversibly sealable opening for unidirectional flow of a liquid. The support frame meets the valve frame on an axis, where the valve frame and the support frame extend from the axis in an opposing direction. The System further includes a catheter, where the valve can be reversibly joined to the catheter at a location between a proximal end and a distal end of the catheter.

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## **Venous Valve Apparatus, System, and Method**

### **Field of the Invention**

The present invention relates generally to apparatus, systems, and methods for use in the vasculature; and more particularly to venous valve apparatus, systems, and methods for use in the peripheral vasculature.

### **Background of the Invention**

The venous system of the legs uses pumps to help return blood to the heart. These pumps are formed from the combined action of various muscle groups and bicuspid one-way valves within the venous vasculature. Venous valves create one way flow to prevent blood from flowing away from the heart and also serve to reduce hydrostatic pressure in the lower legs. When valves fail, blood can pool in the lower legs resulting in swelling and ulcers of the leg. The absence of functioning venous valves can lead to chronic venous insufficiency. Venous insufficiency is a condition in which the veins fail to return blood efficiently to the heart. This condition usually involves one or more of the deep veins. Symptoms include swelling of the legs and pain in the extremities such as a dull aching, heaviness, or cramping.

Techniques for both repairing and replacing the valves exist, but are tedious and require invasive surgical procedures. Direct and indirect valvuoplasty procedures are used to repair damaged valves. Transposition and transplantation are used to replace an incompetent valve. Transposition involves moving a vein with an incompetent valve to a site with a competent valve. Transplantation replaces an incompetent valve with a harvested valve from another venous site. Valves can be transplanted into the venous system, but current devices are not successful enough to see widespread usage.

### **Brief Description of the Drawings**

Figures 1A and 1B illustrate an embodiment of a valve.

Figures 2A and 2B illustrate an embodiment of a valve in an open configuration and an exploded view of the valve.

Figure 3 illustrates an embodiment of a valve in a compressed state.

Figure 4 illustrates an embodiment of a valve in an open configuration.

Figures 5A and 5B illustrate embodiments of elastic regions for valves.

Figure 6 illustrates an embodiment of a system that includes a valve.

Figure 7 illustrates an embodiment of a system that includes a valve.

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### **Detailed Description**

Embodiments of the present invention are directed to an apparatus, system, and method for valve replacement. For example, the apparatus can include a valve that can be used to replace an incompetent valve in a body lumen. Embodiments of  
10 the valve can include a frame and leaflet material that can be implanted through minimally-invasive techniques into the body lumen near an incompetent valve. Embodiments of the apparatus, system, and method for valve replacement may help to maintain antegrade blood flow, while decreasing retrograde blood flow and reduce hydrostatic pressure in a venous system of individuals having venous insufficiency,  
15 such as venous insufficiency in the legs.

The Figures herein follow a numbering convention in which the first digit or digits correspond to the drawing Figure number and the remaining digits identify an element or component in the drawing. Similar elements or components between different Figures may be identified by the use of similar digits. For example, 110 may  
20 reference element "10" in Figure 1, and a similar element may be referenced as 210 in Figure 2.

Figures 1-4 provide illustrations of various embodiments of a valve of the present invention. Generally, valves can be implanted within the fluid passageway of a body lumen, such as for replacement of a valve structure within the body lumen  
25 (e.g., a venous valve), to regulate the flow of a bodily fluid through the body lumen in a single direction. Elements shown in the various embodiments herein can be added, exchanged, and/or eliminated so as to provide any number of additional embodiments of a valve.

Figures 1A and 1B illustrate one embodiment of a valve 100. Valve 100  
30 includes a valve frame 114, a support frame 118, and valve leaflets 119. Valve frame 114 and support frame 118 of valve 100 meet on an axis 120. As discussed herein,

valve frame 114 and support frame 118 extend from axis 120 in an opposing direction and meet so as to form a flexible joint at and/or around axis 120 according to a number of embodiments.

Multiple embodiments exist for valve frame 114 and support frame 118, both of which can include any number of structural configurations. Generally, the valve frame 114 and the support frame 118 can have curved structural configurations, as will be discussed herein. For example, valve frame 114 and support frame 118 can include a first elliptical member 134 and a second elliptical member 138, as illustrated in Figures 1 and 2.

10       The first elliptical member 134 and the second elliptical member 138 meet at a first region 142 and a second region 146, where the first region 142 and the second region 146 are opposite each other across axis 120. The first region 142 and the second region 146 can be located at any number of locations along the first elliptical member 134 and the second elliptical member 138. For example, the first region 142 and the second region 146 can be at or near a minor axis of the first elliptical member 134 and the second elliptical member 138. In an additional embodiment, the first region 142 and the second region 146 can be positioned away from the minor axis of the first elliptical member 134 and the second elliptical member 138.

20       While the term elliptical member is used herein, other shapes are possible for the structural members that help to form a valve of the present invention. For example, the valve frame 114 and the support frame 118 can include circular members that meet at the first region 142 and the second region 146. In one embodiment, the circular members meet at the first region 142 and the second region 146 at, or about, the diameter of the circular members. In an additional embodiment, 25 the first region 142 and the second region 146 can be positioned away from the diameter of the circular members. Other shapes besides elliptical and circular are also possible.

30       The first elliptical member 134 and the second elliptical member 138 can also include either a planar or a non-planar configuration, as will be discussed herein. For example, Figures 1A and 1B illustrate an embodiment in which the first elliptical member 134 and the second elliptical member 138 have a planar configuration 147. As such, the first elliptical member 134 and the second elliptical member 138 each form a portion of the valve frame 114 and the support frame 118. For example, the

first elliptical member 134 and the second elliptical member 138 both include a valve portion 150 and a support portion 154. The valve portion 150 of the first elliptical member 134 and the second elliptical member 138 extend from the first region 142 and the second region 146 to form the valve frame 114. Similarly, the support portion 154 of the first elliptical member 134 and the second elliptical member 138 extend from the first region 142 and the second region 146 to form the support frame 118.

The first elliptical member 134 and the second elliptical member 138 meet at the first region 142 and the second region 146 at an angle 156. In one embodiment, the size of angle 156 can be selected based upon the type of body lumen and the body lumen size in which the valve 100 is to be placed. In an additional embodiment, there can also be a minimum diameter 158 between the first region 142 and the second region 146 that ensures that the first elliptical member 134 and the second elliptical member 138 will have an appropriate expansion force against the inner wall of the body lumen in which the valve 100 is being placed.

Additional factors include, but are not limited to, a longitudinal length 160 and a width 162 of the valve 100. These factors, along with others discussed herein, can be used to provide the angle 156 that is sufficient to ensure that the first elliptical member 134 and the second elliptical member 138 have an appropriate expansion force against an inner wall of the body lumen in which the valve 100 is being placed. For example, the minimum diameter 158 between the first region 142 and the second region 146 and the angle 156 can both be selected to provide an essentially equivalent expansion force on the body lumen 111 at, or around, the first region 142, the second region 146, and by the other portions of the first elliptical member 134 and the second elliptical member 138 that contact the body lumen 111.

The ability of the valve frame 114 and the support frame 118 to form a flexible joint at and/or around axis 120 allows the valve 100 to accommodate changes in body lumen size (e.g., diameter of the body lumen) by increasing or decreasing angle 156. In addition, the valve frame 114 and the support frame 118 also have the ability to flex, as discussed herein, to allow for the distance between the first region 142 and the second region 146 to increase or decrease, thereby further accommodating changes in the body lumen size (e.g., diameter of the body lumen). The valve frame 114 and the support frame 118 can also provide sufficient contact and expansion force with the surface of a body lumen wall to encourage fixation of the valve 100 and to prevent retrograde flow within the body lumen.

Figures 2A and 2B provide a further illustration of a valve 200. Figure 2B illustrates an exploded view of valve 200, where the first elliptical member 234 and the second elliptical member 238 are shown separated so as to better illustrate a non-planar configuration 270 of the elliptical members 234 and 238. In one embodiment, the first elliptical member 234 and the second elliptical member 238 can have a non-planar configuration 270, where the first elliptical member 234 can form the valve frame 214, and the second elliptical member 238 can form the support frame 218. For example, the non-planar configuration 270 of the first elliptical member 234 and the second elliptical member 238 can include a curve 274 at, or near the minor axis 276, to provide for a series of alternating convex curves 278 and concave curves 280. In another embodiment, the curve 274 need not be located at, or about, the minor axis 276 of the first elliptical member 234 and the second elliptical member 238.

The curved structural configuration of the valve frame 214 and the support frame 218 allow for valve 200 to repeatably travel between a collapsed state, as shown in Figure 3, and an expanded state, as shown in Figures 1, 2, and 4 along a first travel path 284. For example, the first elliptical member 234 and the second elliptical member 238 include an elastic region 290, at or adjacent a major axis 292 of the first elliptical member 234 and the second elliptical member 238. The elastic region 290 allows the first elliptical member 234 and the second elliptical member 238 to travel along the first travel path 284, so as to change a length of the minor axis 276 of the first elliptical member 234 and the second elliptical member 238.

Figure 4 illustrates one embodiment in which the elastic region 490 can include an integrated spring 496. For example, the first elliptical member 434 and the second elliptical member 438 can each include the integrated spring 496 in the valve portion 450 and the support portion 454 of the first elliptical member 434 and the second elliptical member 438. In one embodiment, the integrated spring 496 can have a circular or an elliptical coil configuration. Figures 5A and 5B provide additional embodiments of elastic region 590, where elastic region 590 can include a protuberance 598 in the first elliptical member 534 and the second elliptical member 538. Other shapes for the elastic region are also possible.

Referring again to Figures 2A and 2B, the valve frame 214 and the support frame 218 meet at the first region 242 and the second region 246. The valve frame 214 and the support frame 218 meet in the first region 242 and the second region 246 at a flexible connection joint 299. The flexible connection joint 299 allows for the

support frame 218 and the valve frame 214 to travel between the collapsed state, as shown generally in Figure 3, and the expanded state, as shown generally in Figures 1, 2, and 4, along a second travel path 206.

In one embodiment, the flexible connection joint 299 can include the portion  
5 of the first elliptical member 234 and the second elliptical member 238 at which the curve 274 occurs. Figure 4 shows an additional embodiment of the flexible connection joint 499 that includes an integrated spring 410 where the support frame 418 joins to the valve frame 414 on the axis 420. The integrated spring 410 can have a circular or an elliptical coil configuration.

10 The first elliptical member 234 and the second elliptical member 238 can include a variety of cross-sectional shapes and dimensions. For example, cross-sectional shapes for the first elliptical member 234 and the second elliptical member 238 can include, but are not limited to, circular, tubular, I-shaped, T-shaped, oval, and triangular. The first elliptical member 234 and the second elliptical member 238 can  
15 also have a single cross-sectional shape (e.g., all of the first and second elliptical members 234 and 238 have a circular cross-sectional shape). In an additional embodiment, the first elliptical member 234 and the second elliptical member 238 can have two or more cross-sectional shapes (e.g., a circular cross-sectional shape in the elastic region 290 and a different cross-sectional shape in other regions of members  
20 234 and 238).

Valve frame 214 and support frame 218 can further include one or more contiguous members. For example, valve frame 214 and support frame 218 can be formed from a single contiguous member that forms both the first elliptical member 234 and the second elliptical member 238. The single contiguous member can be  
25 bent around an elongate tubular mandrel to form both the valve frame 214 and the support frame 218. The ends of the single contiguous member can then be welded, fused, crimped, or otherwise joined together to form the first elliptical member 234 and the second elliptical member 238. In an additional embodiment, the valve frame 214 and the support frame 218 of the valve can be derived (e.g., laser cut, water cut)  
30 from a single tubular segment. The first elliptical member 234 and the second elliptical member 238 can be heat set by a method as is typically known for the material which forms the members 234 and 238.



In an additional embodiment, the valve frame 214 and the support frame 218 can each be formed from separate contiguous members that are joined as described herein. For example, a first contiguous member can be used to form the first elliptical member 234 and a second contiguous member can be used to form the second elliptical member 238 that is joined to the first elliptical member 234. Methods of joining members 234 and 238 to form the valve frame 214 and the support frame 218 at the first region 242 and the second region 246 can include, but are not limited to, welding, gluing, fusing, and intertwining (e.g., coaxially intertwining the integrated springs of the valve frame 214 and the support frame 218) the members that form the valve frame 214 and the support frame 218.

The valve frame 214 and the support frame 218 can be formed from a biocompatible metal, metal alloy, polymeric material, or combinations thereof, which allow the valve frame 214 and support frame 218 to self-expand and to move radially between the collapsed and expanded state, as discussed herein. To accomplish this, the biocompatible metal, metal alloy, or polymeric material should exhibit a low elastic modulus and a high yield stress for large elastic strains that can recover from elastic deformations. Examples of suitable materials include, but are not limited to, medical grade stainless steel (e.g., 316L), titanium, tantalum, platinum alloys, niobium alloys, cobalt alloys, alginate, or combinations thereof. In an additional embodiment, the valve frame 214 and the support frame 218 may be formed from a shape-memory material. Examples of a suitable shape-memory material include, but are not limited to, alloys of nickel and titanium in specific proportions known in the art as nitinol. Other materials are also possible.

Figure 4 further illustrates an embodiment in which the valve frame 414 and the support frame 418 further include one or more anchoring elements. For example, the one or more anchoring elements can include, but are not limited to, one or more barbs 417 projecting from either, or both, of the valve frame 414 and the support frame 418, as shown in Figure 4.

The valve can further include one or more radiopaque markers (e.g., tabs, sleeves, welds). For example, one or more portions of the valve frame 414, the support frame 418 and/or the barbs 417 can be formed from a radiopaque material. Radiopaque markers can be attached to and/or coated onto one or more locations along the valve frame 414, the support frame 418 and/or the barbs 417. Examples of

radiopaque materials include, but are not limited to, gold, tantalum, and platinum.

The position of the one or more radiopaque markers can be selected so as to provide information on the position, location and orientation of the valve during its implantation.

5           The valve further includes valve leaflets 119 joined to valve frame 114. The valve leaflets 119 can deflect between a closed configuration (Figure 1A) in which retrograde fluid flow through the valve 100 is restricted, and an open configuration (Figure 1B) in which antegrade fluid flow through the valve 100 is permitted. In one embodiment, valve leaflets 119 of the valve are configured to open and close in  
10       response to the fluid motion and/or pressure differential across the valve leaflets 119.

Valve leaflets 119 include surfaces, as discussed herein, defining a reversibly sealable opening 101 for unidirectional flow of a liquid. Valve 100 shown in Figures 1A and 1B provide embodiments in which the surfaces defining the reversibly sealable opening 101 include a first leaflet 124 and a second leaflet 128 coupled to the  
15       valve frame 114 to provide a two-leaflet configuration (i.e., a bicuspid valve) for valve 100. Although the embodiments illustrated in Figures 1A and 1B of the present invention show and describe a two-leaflet configuration for valve 100, designs employing a different number of valve leaflets (e.g., tricuspid valve) are possible.

The valve leaflets 119 can have a variety of sizes and shapes. For example,  
20       each of the valve leaflets 119 (e.g., first leaflet 124 and second leaflet 128) can have a similar size and shape. In addition, each of the valve leaflets 119 can include opposed first and second major surfaces 130 and 132, respectively. Each first major surface 130 of valve leaflets 119 can be oriented to face an upstream end 140 of valve 100. Each of the valve leaflets 119 can further provide sealing surfaces 141 and 144  
25       formed by portions of the first and the second leaflets 124 and 128, respectively, where sealing surfaces 141 and 144 can engage to define the closed configuration (Figure 1A) of valve 100. Sealing surfaces 141 and 144 of valve leaflets 119 can separate to provide for an open configuration (Figure 1B) of valve 100. In an additional example, each of the valve leaflets 119 need not have valve leaflets 119  
30       that are of a similar size and shape (i.e., the valve leaflets can have a different size and shape).

Valve frame 114 can include an open frame construction (i.e., valve frame 114 defines an opening) through which valve leaflets 119 can radially-collapse and

radially-expand. The valve leaflets 119 can be provided over the open frame construction of the valve frame 114 to direct fluid flow through reversibly sealable opening 101 under specific fluid flow conditions. In one embodiment, the material of the valve leaflets 119 coupled to the valve frame 114 can be sufficiently thin and  
5 pliable so as to permit radially-collapsing of the valve leaflets 119 for delivery by catheter to a location within a body lumen.

In one embodiment, each of the valve leaflets 119 includes sufficient excess material spanning valve frame 114 such that fluid pressure (e.g., antegrade flow) acting on the first major surface 130 of the valve leaflets 119 forces the valve 100 into  
10 an open configuration (Figure 1B). Valve leaflets 119 further include arcuate edges 151 and 152 that are positioned adjacent each other along a substantially catenary curve between the first region 142 and the second region 146 in the closed configuration (Figure 1A) of valve 100. Similarly, arcuate edges 151 and 152 can define opening 101 when the valve 100 is in the open configuration (Figure 1B).

In an additional embodiment, in the open configuration the sufficient excess material spanning the valve frame 114 can allow the first and second major surfaces 130 and 132 to take on a semi-tubular structure 159, as shown in Figure 1B, when fluid pressure opens the valve 100. In an additional embodiment, arcuate edge 151 and 152 of valve 100 can open to approximately the full inner diameter of body lumen  
15 111.

Each of the second major surfaces 132 of the valve leaflets 119 can further include a curve imparted thereto so as to provide the second major surface 132 with a concave structure 164. The concave structure 164 allows the valve leaflets 119 to better collect retrograde fluid flow to urge valve leaflets 119 towards the closed  
25 configuration. For example, as retrograde flow begins, the valve leaflets 119 respond by moving towards the center of valve 100. As the valve leaflets 119 approach the center of the device the sealing surfaces 141 and 144 make sufficient contact to effectively close valve 100 and restrict retrograde fluid flow.

In an additional embodiment, the valve leaflets 119 can include one or more support structures. For example, the valve leaflets 119 can include one or more  
30 support ribs having a predetermined shape. In one embodiment, the predetermined shape of the support ribs can include a curved bias so as to provide the valve leaflets 119 with a curved configuration. Support ribs can be constructed of a flexible material and have dimensions (e.g., thickness, width and length) and cross-sectional

shape that allows the support ribs to be flexible when valve leaflets 119 are urged into an open position, and stiff when the valve leaflets 119 are urged into a closed position upon experiencing sufficient back flow pressure from the direction downstream from the valve. In an additional embodiment, support ribs can also be attached to valve frame 114 so as to impart a spring bias to the valve leaflets in either the open or the closed configuration.

The valve leaflets 119 can be constructed of a fluid-impermeable biocompatible material that can be either synthetic or biologic. Possible synthetic materials include, but are not limited to, expanded polytetrafluoroethylene (ePTFE), polytetrafluoroethylene (PTFE), polystyrene-polyisobutylene-polystyrene, polyurethane, segmented poly(carbonate-urethane), Dacron, polyethylene (PE), polyethylene terephthalate (PET), silk, urethane, Rayon, Silicone, or the like. Possible biologic materials include, but are not limited to, autologous, allogeneic or xenograft material. These include explanted veins and decellularized basement membrane materials, such as small intestine submucosa (SIS) or umbilical vein.

Valve leaflets 119 can be coupled to the various embodiments of valve frame 114, as described herein, in any number of ways. For example, a variety of fasteners can be used to couple the material of the valve leaflets 119 to the valve frame 114. In one embodiment, the material of the valve leaflets 119 can be wrapped at least partially around the valve frame 114 and coupled using the fastener. Fasteners can include, but are not limited to, biocompatible staples, glues, and sutures. In an additional embodiment, valve leaflets 119 can be coupled to the various embodiments of valve frame 114 through the use of heat sealing, solvent bonding, adhesive bonding, or welding the valve leaflets 119 to either a portion of the valve leaflet 119 (i.e., itself) and/or the valve frame 114. Valve leaflets 119 can also be attached to valve frame 114 according to the methods described in U. S. Patent Application Publication US 2002/0178570 to Sogard et al., which is hereby incorporated by reference in its entirety.

The valve leaflets 119 may also be treated and/or coated with any number of surface or material treatments. For example, the valve leaflets 119, the valve frame 114, and/or the support frame 116 can be treated with a non-thrombogenic biocompatible material, as are known or will be known. In an additional example, the valve leaflets 119, the valve frame 114, and/or the support frame 116 can be treated with one or more biologically active compounds and/or materials that may promote

and/or prevent endothelialization of the valve leaflets 119. Similarly, each of the valve leaflets 119 may be seeded and covered with cultured tissue cells (e.g., endothelial cells) derived from either a donor or the host patient which are attached to the valve leaflets 119. The cultured tissue cells may be initially positioned to extend either  
5 partially or fully over the valve leaflets 119.

Examples of possible non-thrombogenic biocompatible material coatings include block copolymers comprising at least one A block and at least one B block. The A blocks can include soft elastomeric blocks, which are based upon one or more polyolefins, or other polymer with a glass transition temperature at or below room  
10 temperature. For example, the A blocks can be polyolefinic blocks having alternating quaternary and secondary carbons of the general formulation:  $-(CRR'-CH_2)_n-$ , where R and R' are, independently, linear or branched aliphatic groups such as methyl, ethyl, propyl, isopropyl, butyl, isobutyl and so forth, or represent cyclic aliphatic groups such as cyclohexane, cyclopentane, and the like, either with or without pendant  
15 groups. Examples of polyolefinic blocks include polymeric blocks of isobutylene  $H_2C=C(CH_3)_2$ , (i.e., where R and R' are methyl groups). Other examples of A blocks include silicone rubber blocks and acrylate rubber blocks.

The B blocks can include hard thermoplastic blocks with glass transition temperatures significantly higher than the elastomeric A blocks which, when  
20 combined with the soft A blocks, are capable of, beside other things, altering or adjusting the hardness of the resulting copolymer to achieve a desired combination of qualities. Examples of B blocks include polymers of methacrylates or polymers of vinyl aromatics. More specific examples of B blocks include blocks that can be formed from monomers of styrene, styrene derivatives (e.g.,  $\alpha$ -methylstyrene, ring-alkylated styrenes or ring-halogenated styrenes or other substituted styrenes where  
25 one or more substituents are present on the aromatic ring) or mixtures of the same, collectively referred to herein as "styrenic blocks" or "polystyrenic blocks", or can be formed from monomers of methylmethacrylate, ethylmethacrylate, hydroxyethyl methacrylate or mixtures of the same.

30 The block copolymers are provided in a variety of architectures, including cyclic, linear, and branched architectures. Branched architectures include star-shaped architectures (e.g., architectures in which three or more chains emanate from a single region), comb architectures (e.g., copolymers having a main chain and a plurality of

side chains), and dendritic architectures (including arborescent or hyperbranched copolymers).

Some examples of such block copolymers include, but are not limited to, the following: (a) BA (linear diblock), (b) BAB or ABA (linear triblock), (c) B(AB)<sub>n</sub> or A(BA)<sub>n</sub> (linear alternating block), or (d) X-(AB)<sub>n</sub> or X-(BA)<sub>n</sub> (includes diblock, triblock and other radial block copolymers), where n is a positive whole number and X is a starting seed, or initiator, molecule. One specific group of polymers have X-(AB)<sub>n</sub> structures, which are frequently referred to as diblock copolymers and triblock copolymers where n=1 and n=2, respectively (this terminology disregards the presence of the starting seed molecule, for example, treating A-X-A as a single A block, with the triblock therefore denoted as BAB). One example of a polymer from this group includes polystyrene-polyisobutylene-polystyrene triblock copolymer (SIBS). Where n=3 or more, these structures are commonly referred to as star-shaped block copolymers. Other examples of block polymers include branched block copolymers such as dendritic block copolymers, wherein at least one of the A and B blocks is branched, for instance, where the A blocks are branched and are capped by the B blocks.

Figure 6 illustrates one embodiment of a system 601. System 601 includes at least one of the valves, as described herein, and a catheter 608. The catheter 608 includes an elongate body 609 having a proximal end 613 and a distal end 615, where a valve 600 can be located between the proximal end 613 and distal end 615. The catheter 608 can further include a lumen 621 longitudinally extending to the distal end 615. In one embodiment, lumen 621 extends between proximal end 613 and distal end 615 of catheter 608. The catheter 608 can further include a guidewire lumen 631 that extends within the elongate body 609, where the guidewire lumen 631 can receive a guidewire for positioning the catheter 608 and the valve 600 within a body lumen (e.g., a vein of a patient).

The system 601 can further include a deployment shaft 635 positioned within lumen 621, and a sheath 639 positioned adjacent the distal end 615. In one embodiment, the valve 600 can be positioned at least partially within the sheath 639 and adjacent the deployment shaft 635. The deployment shaft 635 can be moved within the lumen 621 to deploy valve 600. For example, deployment shaft 635 can be used to push valve 600 from sheath 639 in deploying valve 600.

Figure 7 illustrates an additional embodiment of the system 701. The catheter 708 includes elongate body 709, lumen 721, a retraction system 745 and a retractable sheath 743. The retractable sheath 743 can be positioned over at least a portion of the elongate body 709, where the retractable sheath 743 can move longitudinally along the elongate body 709. The valve 700 can be positioned at least partially within the retractable sheath 743, where the retractable sheath 743 moves along the elongate body 709 to deploy the valve 700. In one embodiment, retraction system 745 includes one or more wires coupled to the retractable sheath 743, where the wires are positioned at least partially within and extend through lumen 721 in the elongate body 709. Wires of the retraction system 745 can then be used to retract the retractable sheath 743 in deploying valve 700.

Embodiments of the present invention can further include methods of forming the valve of the present invention. For example, the methods can include forming a valve, as discussed herein. Valve can include the valve frame, the valve leaflets joined to the valve frame, where the valve leaflets includes surfaces defining a reversibly sealable opening for unidirectional flow of a liquid. Valve can further include the support frame that meets the valve frame on an axis from which the valve frame and the support frame extend in an opposing direction.

Valve can then be reversibly joined to the catheter. Reversibly joining valve to the catheter can include altering the shape of valve from a first shape, for example an expanded state, to join valve and the catheter. For example, in reversibly joining valve and the catheter, the shape of valve can be altered into the compressed state. Valve can be reversibly joined with the catheter by positioning valve in the compressed state at least partially within the sheath of the catheter.

In one embodiment, positioning valve at least partially within the sheath of the catheter includes positioning valve in the compressed state adjacent the deployment shaft of the catheter. In an another embodiment, the sheath of the catheter functions as a retractable sheath, where valve in the compressed state can be reversibly joined with the catheter by positioning valve at least partially within the reversible sheath of the catheter.

Embodiments of the present invention can also include positioning and deploying the valve of the present invention. For example, at least part of a catheter that includes valve can be positioned at a predetermined location. In one embodiment, the predetermined location can include a position within a body lumen

of a venous system of a patient. For example, positioning at least part of the catheter at the predetermined location includes positioning at least part of the catheter within a vein of a leg.

In one embodiment, positioning the catheter that includes valve within the  
5 body lumen of a venous system includes introducing the catheter into the venous system of the patient using minimally invasive percutaneous, transluminal catheter based delivery system. For example, a guidewire can be positioned within a body lumen of a patient that includes the predetermined location. The catheter, including valve can be positioned over the guidewire and the catheter advanced so as to position  
10 the valve at or adjacent the predetermined location. In one embodiment, radiopaque markers on the catheter and/or the valve can be used to help locate and position the valve.

The valve can be deployed from the catheter at the predetermined location. In one embodiment, valve of the present invention can be deployed and placed in any  
15 number of vascular locations. For example, valve can be deployed and placed within a major vein of a patient's leg. In one embodiment, major veins include, but are not limited to, those of the peripheral venous system. Examples of veins in the peripheral venous system include, but are not limited to, the superficial veins such as the short saphenous vein and the greater saphenous vein, and the veins of the deep venous  
20 system, such as the popliteal vein and the femoral vein.

As discussed herein, the valve can be deployed from the catheter in any number of ways. For example, the catheter can include a retractable sheath in which valve can be at least partially housed. Valve can be deployed by retracting the retractable sheath of the catheter, where the valve self-expands to be positioned at the  
25 predetermined location. In an additional example, the catheter can include a deployment shaft and sheath in which valve can be at least partially housed adjacent the deployment shaft. Valve can be deployed by moving the deployment shaft through the catheter to deploy valve from the sheath, where the valve self-expands to be positioned at the predetermined location.

30 In one embodiment, valve can provide sufficient contact and expansion force against the body lumen wall to prevent retrograde flow between the valve and the body lumen wall. For example, the valve can be selected to have a larger expansion diameter than the diameter of the inner wall of the body lumen. This can then allow valve to exert a force on the body lumen wall and accommodate changes in the body



lumen diameter, while maintaining the proper placement of valve. As described herein, the valve can engage the lumen so as to reduce the volume of retrograde flow through and around valve. It is, however, understood that some leaking or fluid flow may occur between the valve and the body lumen and/or through valve leaflets.

5           In addition, the use of both the valve frame and the support frame of valve can provide a self centering aspect to valve within a body lumen. In one embodiment, the self centering aspect resulting from the support frame, in conjunction with valve frame, may allow valve to maintain a substantially coaxial alignment with the body lumen (e.g., such as a vein) as valve leaflets deflect between the open and closed  
10 configurations so as to better seal reversible opening when valve is closed.

          While the present invention has been shown and described in detail above, it will be clear to the person skilled in the art that changes and modifications may be made without departing from the spirit and scope of the invention. As such, that which is set forth in the foregoing description and accompanying drawings is offered  
15 by way of illustration only and not as a limitation. The actual scope of the invention is intended to be defined by the following claims, along with the full range of equivalents to which such claims are entitled.

          In addition, one of ordinary skill in the art will appreciate upon reading and understanding this disclosure that other variations for the invention described herein  
20 can be included within the scope of the present invention.

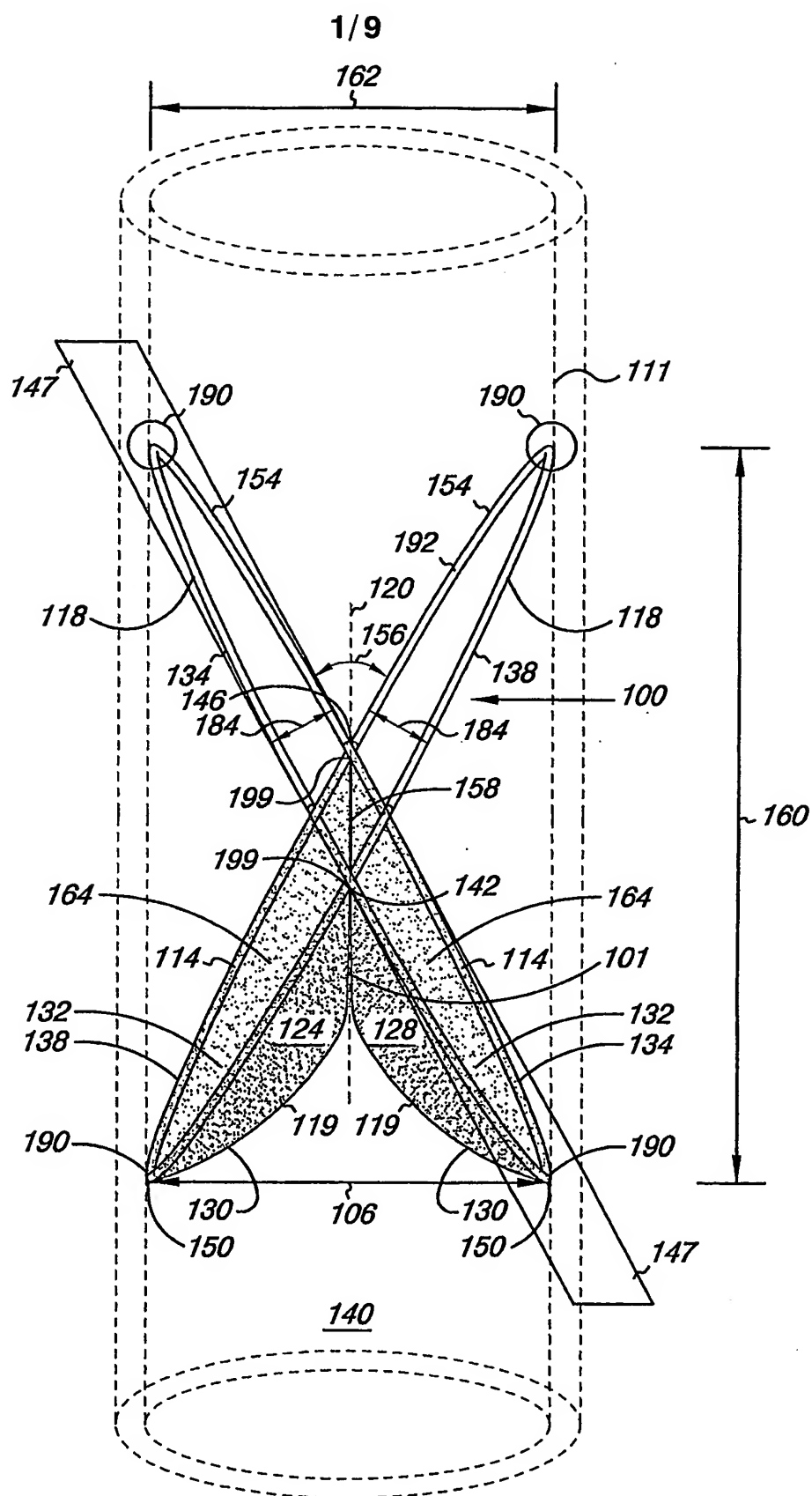
          In the foregoing Detailed Description, various features are grouped together in several embodiments for the purpose of streamlining the disclosure. This method of disclosure is not to be interpreted as reflecting an intention that the embodiments of the invention require more features than are expressly recited in each claim. Rather,  
25 as the following claims reflect, inventive subject matter lies in less than all features of a single disclosed embodiment. Thus, the following claims are hereby incorporated into the Detailed Description, with each claim standing on its own as a separate embodiment.

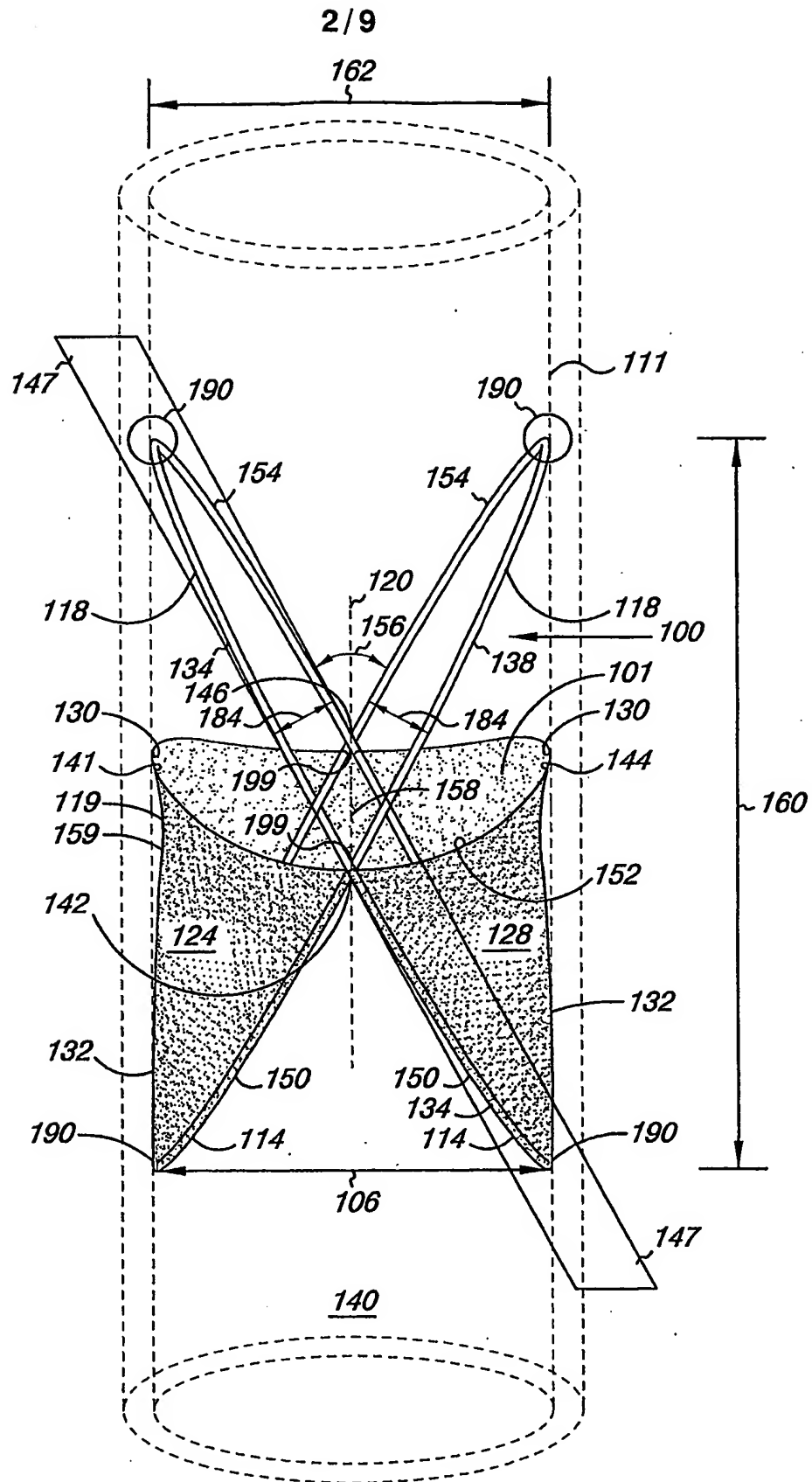
WHAT IS CLAIMED IS:

1. A valve, comprising:  
a valve frame;  
a valve leaflet joined to the valve frame, wherein the valve leaflet includes surfaces defining a reversibly sealable opening for unidirectional flow of a liquid; and  
a support frame, where the support frame meets the valve frame on an axis, and where the valve frame and the support frame extend from the axis in an opposing direction.
2. The valve of claim 1, wherein the valve frame and the support frame include a first elliptical member and a second elliptical member that meet at a first region and a second region opposite the first region on the axis.
3. The valve of claim 2, wherein each of the first elliptical member and the second elliptical member include both a valve portion extending from the first region and the second region to form the valve frame, and a support portion extending from the first region and the second region in the opposing direction to form the support frame.
4. The valve of claim 3, wherein the valve portion includes the valve leaflet and a portion of both the first elliptical member and the second elliptical member, and the support portion includes a portion of both the first elliptical member and the second elliptical member.
5. The valve of claim 2, wherein the first elliptical member forms the valve frame and the second elliptical member forms the support frame.
6. The valve of claim 1, wherein the valve leaflet includes a first leaflet and a second leaflet attached to the valve frame, the first leaflet and the second leaflet including a surface with a semi-tubular structure when fluid opens the reversibly sealable opening and a concave structure when fluid closes the reversibly sealable opening.

7. The valve of claim 1, further including a catheter including a proximal end and a distal end, the valve located between the proximal end and distal end of the catheter.
8. The valve of claim 7, wherein the catheter includes a lumen longitudinally extending to the distal end, a deployment shaft positioned within the lumen, and a sheath positioned adjacent the distal end, the valve positioned at least partially within the sheath and adjacent the deployment shaft, wherein the deployment shaft moves within the lumen to deploy the valve.
9. The system of claim 7, wherein the catheter includes an elongate body and a retractable sheath over at least a portion of the elongate body, the valve positioned at least partially within the retractable sheath, wherein the retractable sheath moves along the elongate body to deploy the valve.
10. A method, comprising:
  - forming a valve that includes:
    - a valve frame;
    - a valve leaflet joined to the valve frame, wherein the valve leaflet includes surfaces defining a reversibly sealable opening for unidirectional flow of a liquid; and
    - a support frame, where the support frame meets the valve frame on an axis, and where the valve frame and the support frame extend from the axis in an opposing direction.
11. The method of claim 10, further including reversibly joining the valve and a catheter, wherein the valve includes a first shape, and wherein reversibly joining the valve and the catheter includes altering the first shape of the valve to join the valve and the catheter.
12. The method of claim 10, further including reversibly joining the valve and a catheter, wherein reversibly joining the valve and the catheter includes positioning the valve at least partially within a sheath of the catheter.

13. The method of claim 12, wherein positioning the valve at least partially within a sheath of the catheter include positioning the valve adjacent a deployment shaft of the catheter.
14. The method of claim 12, wherein the sheath includes a retractable sheath of the catheter.
15. The method of claim 10, wherein the valve frame and the support frame include a first elliptical member and a second elliptical member that meet at a first region and a second region opposite the first region on the axis.
16. The method of claim 15, wherein each of the first elliptical member and the second elliptical member include both a valve portion extending from the first region and the second region to form the valve frame, and a support portion extending from the first region and the second region in the opposing direction to form the support frame.
17. The method of claim 15, wherein the first elliptical member forms the valve frame and the second elliptical member forms the support frame.
18. The method of claim 10, wherein the valve leaflet includes a first leaflet and a second leaflet attached to the valve frame, the first leaflet and the second leaflet including a surface with a tubular structure when fluid opens the reversibly sealable opening and a concave structure when fluid closes the reversibly sealable opening.



*Fig. 1B*

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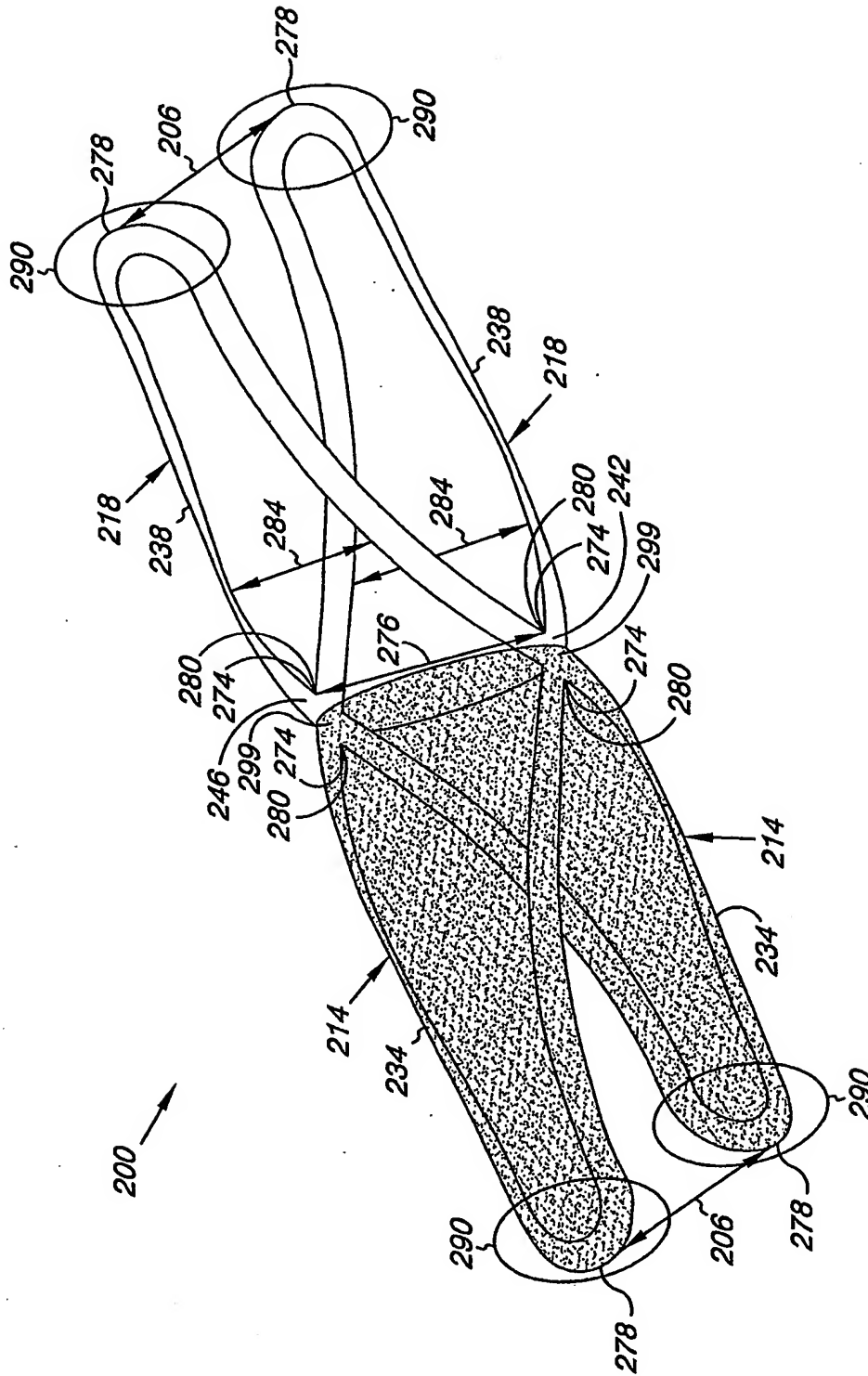


Fig. 2A

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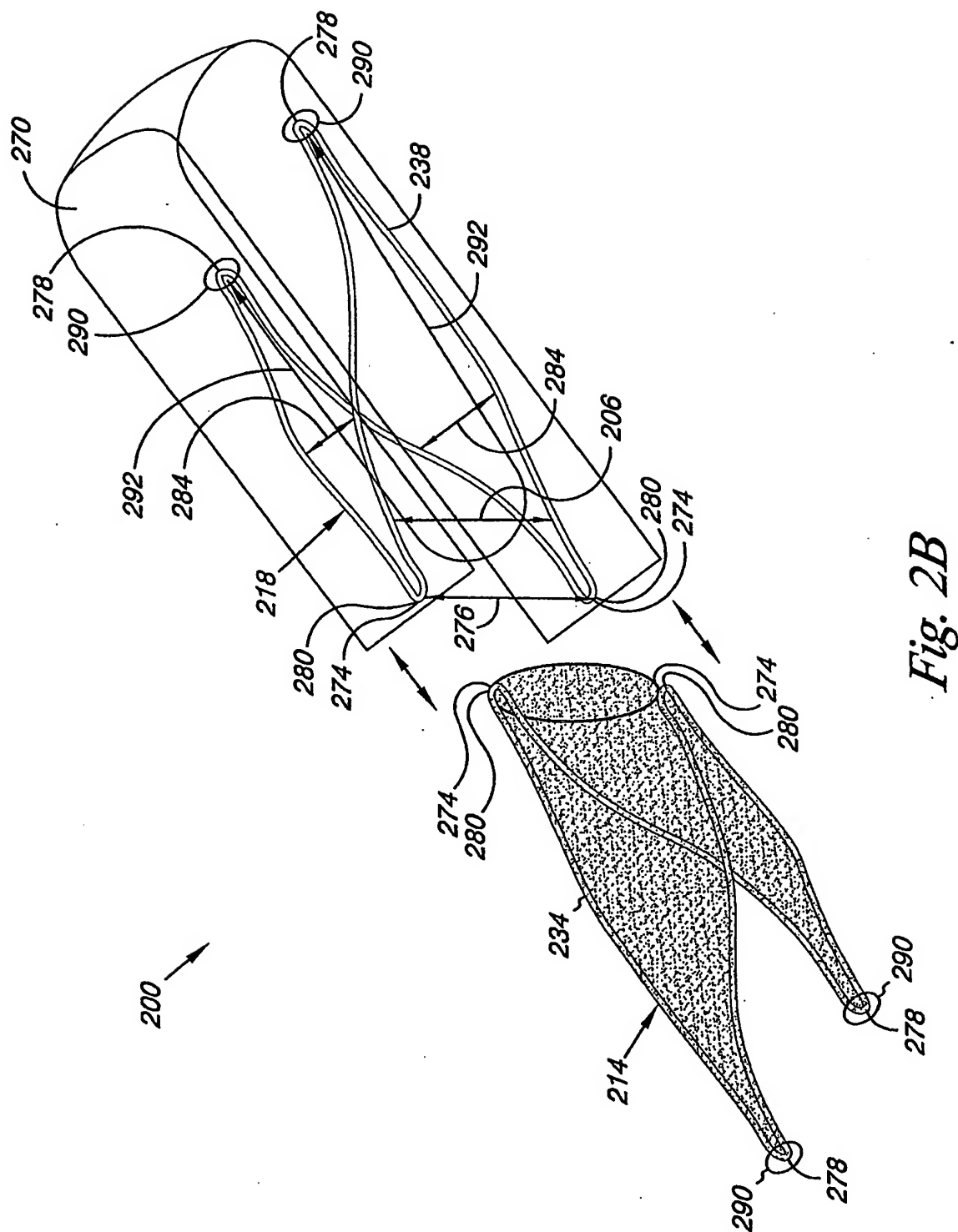
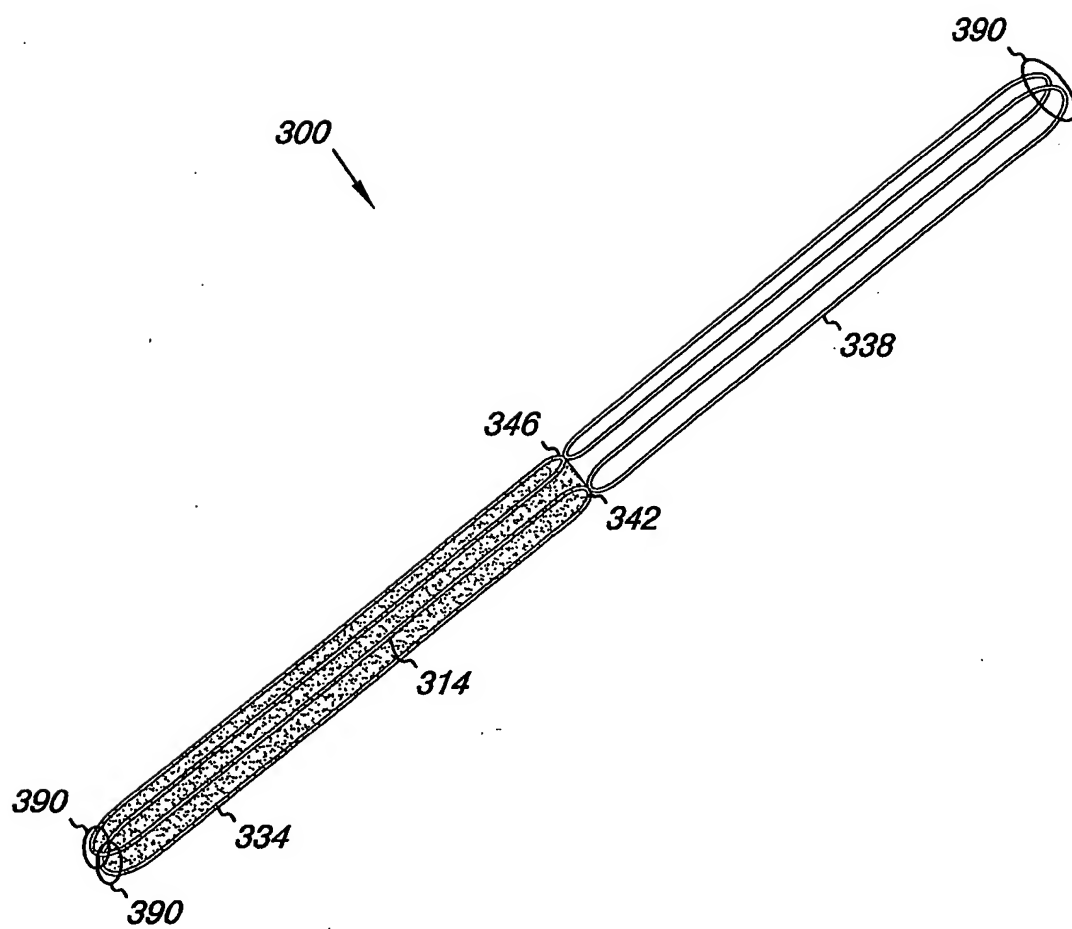


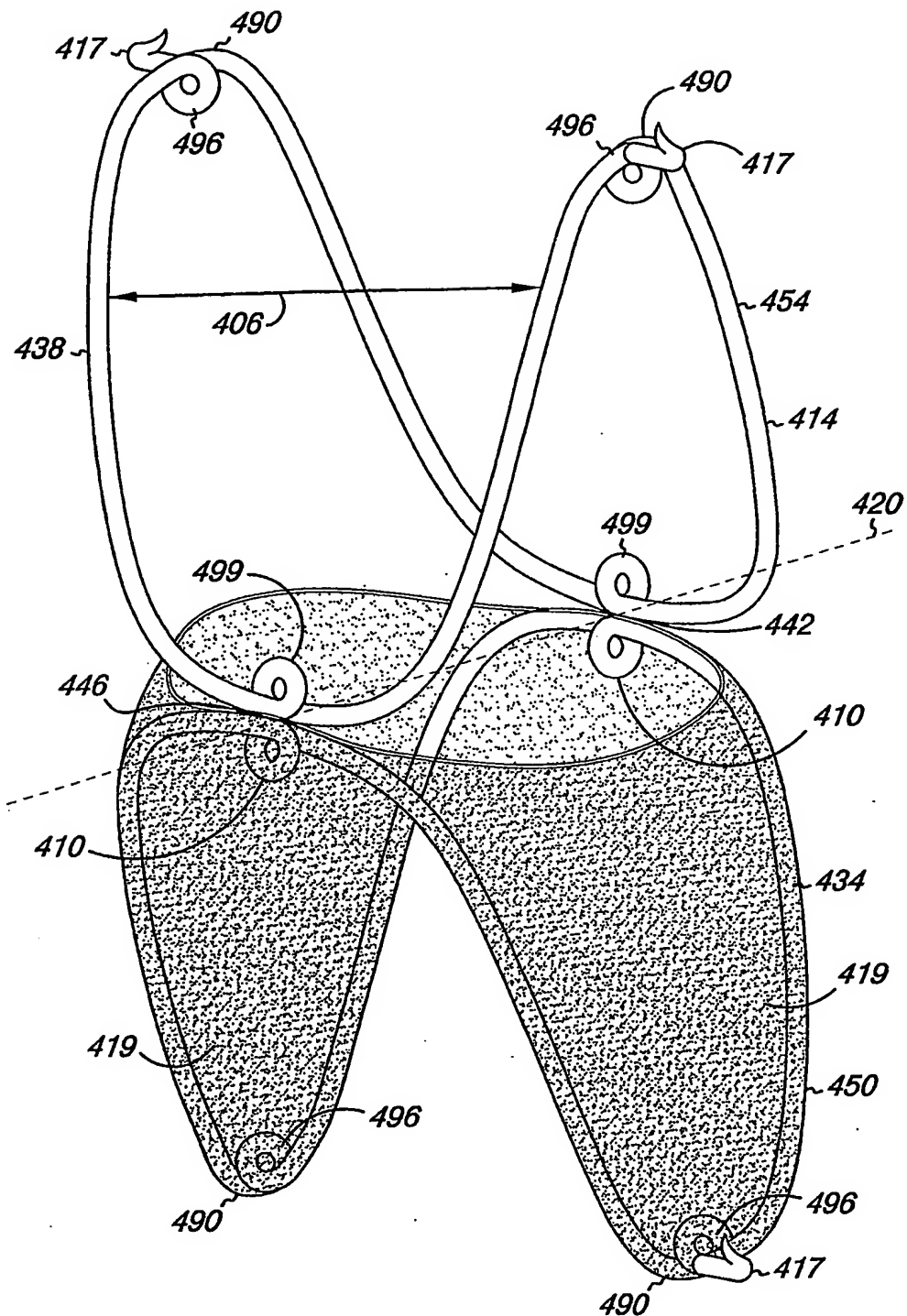
Fig. 2B



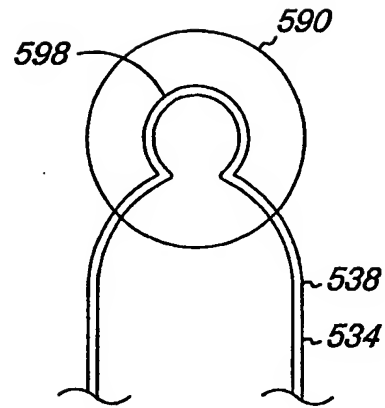
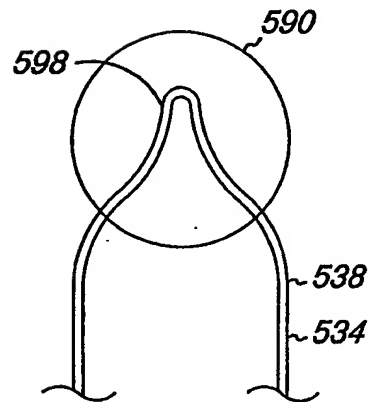
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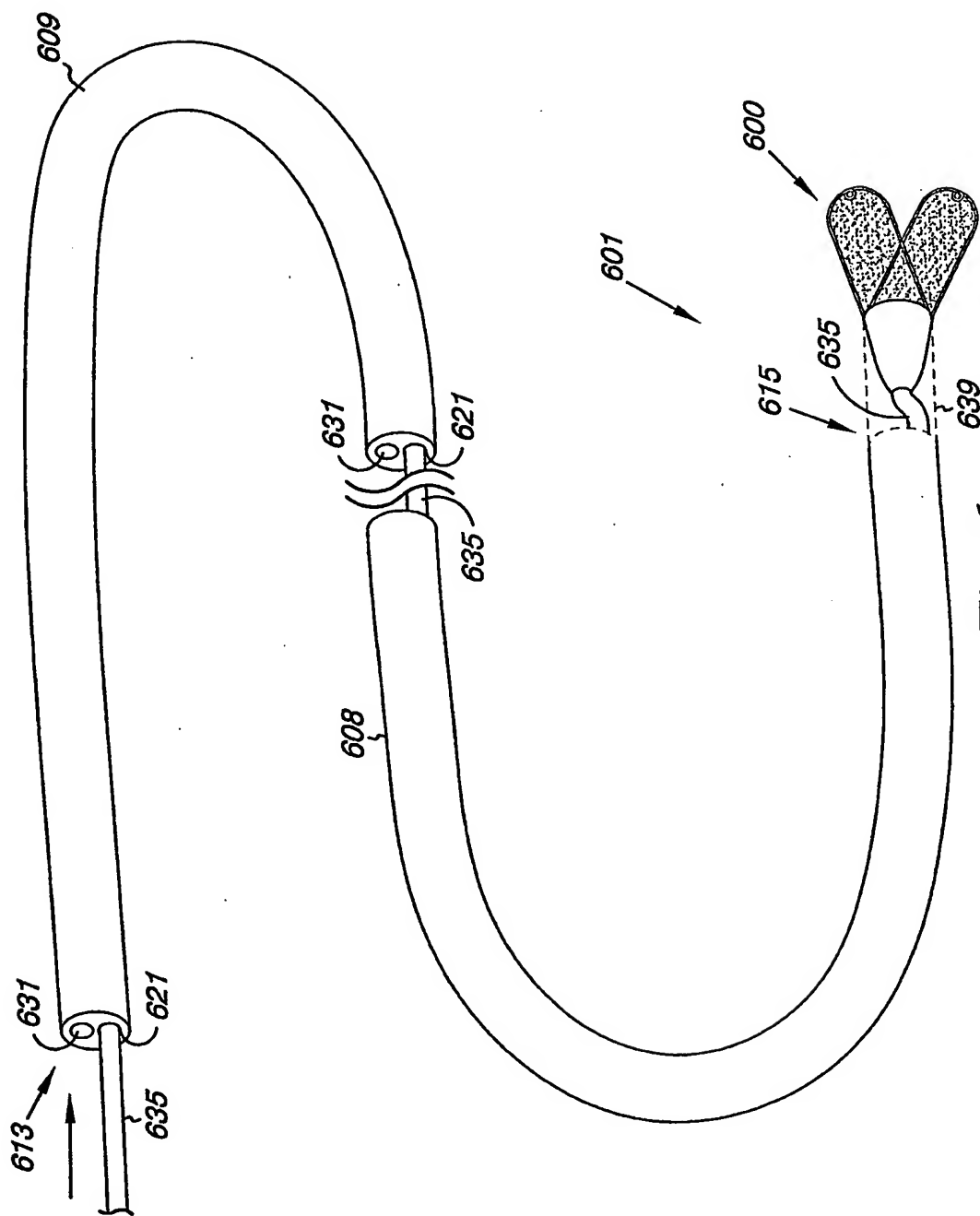
*Fig. 3*

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*Fig. 4*

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*Fig. 5A**Fig. 5B*



*Fig. 6*

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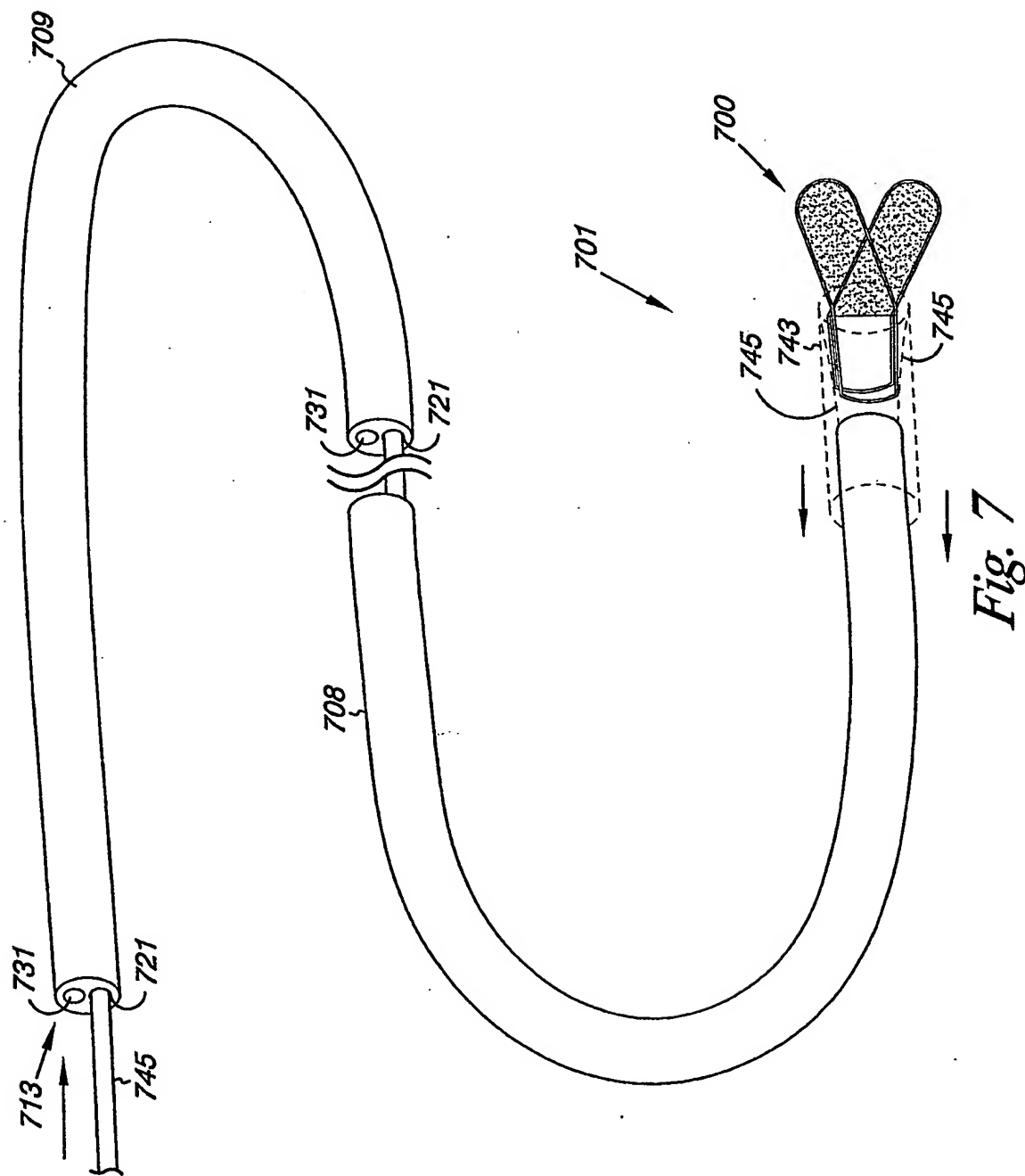


Fig. 7

## INTERNATIONAL SEARCH REPORT

International Application No

PCT/US2004/042057

A. CLASSIFICATION OF SUBJECT MATTER  
 IPC 7 A61F2/24 A61M39/00

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61F A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the International search (name of data base and, where practical, search terms used)

EPO-Internal

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 667 133 A (CAMILLI, SANTE) 16 August 1995 (1995-08-16) column 4, line 7 - column 6, line 55; figures	1-18
P, X	WO 2004/016200 A (COOK INCORPORATED; OREGON HEALTH AND SCIENCE UNIVERSITY; MED INSTITUTE) 26 February 2004 (2004-02-26) the whole document	1-18
A	US 2001/011187 A1 (PAVCHNIK DUSAN ET AL) 2 August 2001 (2001-08-02) paragraphs '0026! - '0037!; figures	1-18

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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Date of the actual completion of the international search

2 March 2005

Date of mailing of the international search report

16/03/2005

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# INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

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